K122085

510(k) Summary for the

Spine 360 Cervical Interbody Fusion System

OCT 17 2012

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the Spine 360 Interbody Fusion System.
Date Prepared: July 12, 2012

1. **Submitter:**
Spine 360
5000 Plaza on the Lake, Suite 305
Austin, TX 78746

Contact Person:
Dave Lamb
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5000 Plaza on the Lake Suite 305
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Telephone: 512-327-6400 ext. 24

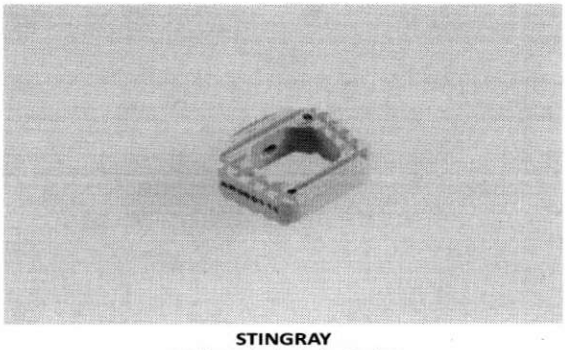
Establishment Registration Number 3005841736

2. **Trade name:** Spine 360 Cervical Interbody Fusion System
Common Name: intervertebral body fusion device
Classification Name: intervertebral body fusion device - cervical
21 CFR section 888.3080
ODP
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
Spine 360 Interbody Fusion System is substantially equivalent to the following devices.
   - US Spine Phantom Plus Cage (K082801)
   - Zimmer BAK/C Vista Interbody Fusion (P980048 S3)

4. **Description of the device:**
The Stingray Cervical Cage was developed as an intercorporal implant for anterior cervical spondylosis. Stingray is a system of wedge-shaped implants and instruments designed for anterior cervical interbody fusion (ACIF). In the lateral view, the implant has a 3.5° lordotic form. The Stingray Cervical Cage has a flat top and bottom.

Materials:
PEEK-OPTIMA LT1 polymer (ASTM F2026 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications) and tantalum according to ASTM F560.



STINGRAY
ACIF Interbody Fusion Device
7° lordotic form 12 x 14mm - 5 to 22mm heights
5° lordotic form 14 x 17mm- 6 to 11mm heights
Anti-migration ridges on its superior and inferior surfaces
large window allows bone growth to form
two tantalum x-ray markers for radiographic identification

5. Substantial equivalence claimed to predicate devices

Spine 360 Cervical Interbody Fusion System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances. The table below compares the features and characteristics of the Spine 360 Cervical Interbody Fusion System to these predicate devices.

Device	Spine 360 Stingray	Phantom Plus Cage	BAKc
510(k) number	--	K082801	P980048 S3
Intended use	Per 888.3080	Per 888.3080	Per 888.3080
Bone graft cavity	Yes	Yes	Yes
Ridges	Yes	Yes	Yes
X-ray markers	Yes	Yes	Yes
Raw material	PEEK Optima LT1	PEEK Optima LT1	Ti-6Al-4Vd
Sterility	Provided non-sterile Steam sterilized at hospital	Provided non-sterile Steam sterilized at hospital	Provided gamma sterilized
Sizes –Height	5-12mm	6-12mm	6-12mm
Sizes-Depth	12mm	11mm	12mm
Sizes-Width	12mm-14mm	14mm	10mm-17mm

6. Intended Use:

The Spine 360 Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The Spine 360 Cervical Interbody Fusion System implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to T1 disc levels using autograft bone. The Spine 360 Cervical Interbody Fusion System implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

7. Non-clinical Test Summary:

The following tests were conducted:

Static Compression	F2077-11
Static Compression Shear	F2077-11
Static Compression Torsion	F2077-11
Subsidence	F2267-04
Expulsion	
Dynamic Compression	F2077-11
Dynamic Compression Shear	F2077-11
Dynamic Torsion	F2077-11

8. Clinical Test Summary

No clinical studies were performed

9. Conclusions from Non-clinical tests

A direct comparison of test results of the Spine360 Stingray and predicate devices demonstrated the Stingray was equivalent or superior to the predicates tested. The Spine360 Stingray Cervical Interbody Fusion Device exceeded pre-determined test criteria as well as the biomechanical tissue tolerances of the cervical spine FSU. (see report OKT_TR380-0811-13596)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Omni Surgical, LP DBA Spine360
% Mr. Dave Lamb
Quality and Regulatory Affairs
5000 Plaza on the Lake, Suite 305
Austin, Texas 78746

OCT 17 2012

Re: K122085
Trade/Device Name: Spine360 Stingray Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: September 17, 2012
Received: September 17, 2012

Dear Mr. Lamb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122085

Device Name: Spine360 Stingray Cervical Interbody Fusion System

The Spine360 Stingray Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The Spine 360 Cervical Interbody Fusion System implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to T1 disc levels using autograft bone. The Spine 360 Cervical Interbody Fusion System implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122085